REMARKS

Claims presented for prosecution in this Application are claims 1-5, 7, 9-14, and 16-21. Claims 3-5, 7, 16, and 18 remain withdrawn. Claims 1 and 19-21 are amended herein. Support for the recitations may be found in the present specification at, *inter alia*, page 6, lines 3-5 and the examples. In view of Applicants' remarks below, Applicants respectfully submit that claims 1-2, 9-14, 17, and 19-21 are in condition for allowance. Accordingly, Applicants respectfully request that the present Response be considered and entered, the rejections to the claims be withdrawn, and that the case now be passed to issue.

Allowable Subject Matter

Applicants acknowledge the indication of allowable subject matter of claim 19 to the extent limited to the elected species. However, for the reasons indicated below, all pending claims are believed to be directed to allowable subject matter.

Specification

The Examiner requests that Applicants submit a paper copy of the sequence listing on page 2, line 25 and a copy in the Computer Reader Format of the same. Applicants note that the Amendment filed on February 6, 2002 addresses this issue. Applicants have enclosed a copy of the February 6th Amendment for the Examiner's convenience. Thus, Applicants respectfully request removal of the outstanding issue.

Issues under 35 U.S.C. § 102(b)

Claims 1, 2, 9-14, 17, and 19-21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Paik et al., *J. Nucl. Med.*, Vol. 24, pp. 1158-1163 (1983) (see pages 3-5 of the Office Action). In response, Applicants respectfully assert that the Paik et al. reference does not disclose each and every aspect of independent claims 1 and 19-21.

As recited in instantly pending claims 1 and 19-21, the present invention is directed to a "process for producing an amide compound, which comprises reacting a compound having an amino group with a polyaminopolycarboxylic acid anhydride in the presence of the polyaminopolycarboxylic acid" wherein "***the polyaminopolycarboxylic acid anhydride is added to a mixture of the compound having an amino group and the polyaminopolycarboxylic acid, or the compound having an amino group and the polyaminopolycarboxylic acid anhydride are added to the polyaminopolycarboxylic acid; and wherein the polyaminopolycarboxylic group of both said acid and said acid anhydride are the same.***" (emphasis added).

Not all instantly claimed features are disclosed in the Paik et al. reference. Specifically, the claimed processes are different from the disclosed process of Paik et al. Applicants have previously amended claims 1 and 19-21 to recite that "the polyaminopolycarboxylic acid anhydride is added to a mixture of the compound having an amino group and the polyaminopolycarboxylic acid, or the compound having an amino group and the polyaminopolycarboxylic acid anhydride are added to the polyaminopolycarboxylic acid."

In stark contrast, the cited reference clearly fails to teach or suggest such an embodiment. The cited reference teaches that the DTPA anhydride hydrolyzes in the presence of water (page 1158, column 2), with the requisite reaction occurring in the presence of polyaminopolycarboxylic acid due to the presence of hydrolyzed product of the DTPA anhydride being present in the reaction mixture. In other words, any acid which is present is due to its *in situ* formation.

As amended, the simultaneous addition of the polyaminopolycarboxylic acid anhydride and polyaminopolycarboxylic acid is not encompassed by the claims. Regardless, Applicants respectfully traverse the Examiner's assertion regarding the presence of 0.1% impurity of unreacted DTPA or hydrolyzed anhydride compounds. The Paik et al. reference does not disclose such impurities.

Furthermore, the present application clearly defines polyaminopolycarboxylic acid anhydride. The bicarbonate of the Paik et al. reference is not a polycarboxylic acid. The Examiner asserts that the claim as recited does not imply that the polyaminopolycarboxylic anhydride is derived from the same polyaminopolycarboxylic acid. Applicants have amended the claims to further clarify the invention that "the polyaminopolycarboxylic group of both said acid and said acid anhydride are the same."

With the respect to the Examiner's reliance on Le Chatelier's Principle, Applicants respectfully traverse. The polyaminopolycarboxylic acid cannot easily be converted to its anhydride in the present process. The addition of polyaminopolycarboxylic acid does not favor the formation of polyaminopolycarboxylic acid anhydride in the reaction condition. It cannot

properly be said that the addition of polyaminopolycarboxylic acid assists the formation of the desired product. The scheme illustrated on page 8 of the Office Action does not cover the other side reactions occurring in the reaction mixture. Other side reactions are present in the reaction mixture, and the real reaction in the mixture is rather complex.

Thus, the present invention is different from Paik et al. for at least these reasons stated above. The rejection under 35 U.S.C. § 102(b) is thus without basis and should be withdrawn.

CONCLUSION

Based upon the amendments and remarks presented herein, the Examiner is respectfully requested to issue a Notice of Allowance clearly indicating that pending claims 1-2, 9-14, 17, and 19-21 are allowed and patentable under the provisions of Title 35 of the United States Code.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact John W. Bailey (Reg. No. 32,881) at the telephone number below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated: APR 08 2008

Respectfully submitted,

By _____
John W. Bailey
Registration No.: 32,881
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road, Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicants

Attachment: Amendment filed on February 6, 2002

JWB/CMR/amm

#8

BOX SEQUENCE
PATENT
2185-577P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant:	Takano & Nakamura	Conf.:	2971
Appl. No.:	09/971,929	Group:	TO BE ASSIGNED
Filed:	October 9, 2001	Examiner:	TO BE ASSIGNED
For:	PROCESS FOR PRODUCING AN AMIDE COMPOUND		

AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

February 6, 2002

Sir:

In response to the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures mailed December 7, 2001, the following amendments and remarks are respectfully submitted in connection with the above-identified application.

In the Specification:

Please replace the paragraph beginning on page 2, line 24, with the following rewritten paragraph:

Examples of the peptide include, for example, a synthetic peptide such as Pyr-Lys-Arg-Pro-Ser-Gln-Arg-Ser-Lys-Tyr-Leu (SEQ ID NO:1), D-Phe-octreotide, polylysine or the like, a hormone such as oxytocin, bradykinin or the like, and an antibiotic such as valinomycin, colistin or the like.

Please insert the Substitute Sequence Listing enclosed herewith immediately after the abstract.

In the Claims:

16. (Amended) The process according to claim 1, wherein the compound having an amino group is a chitosan tri- to deca-saccharide, a chitosan tri- to deca-saccharide having a reduced terminal reducing group, a galactosamine tri- to deca-saccharide, a galactosamine tri- to deca-saccharide having a reduced terminal reducing group, serum albumin, fibrinogen, galactosyl serum albumin, amylase, pepsin, IgG, Fab, Fab', thyroid-stimulating hormone, a growth hormone, prolamine, glutelin, Pyr-Lys-Arg-Pro-Ser-Gln-Arg-Ser-Lys-Tyr-Leu (SEQ ID NO:1), D-Phe-octreotide, polylysine, oxytocin, bradykinin, valinomycin, colistin, an α-amino acid, a β-amino acid, a γ-amino acid, aniline, 4-methylaniline, 4-octylaniline, ethylamine, n-propylamine, isopropylamine, n-butylamine, sec-butylamine, isobutylamine, tert-butylamine, n-octylamine, n-decylamine, (1-naphthylmethyl)amine, N-methylaniline, N-methyl-4-ethylaniline, N-methyl-4-octylaniline, diethylamine, N-ethyl-N-propylamine, ethylenediamine, dansylethylenediamine, dansylhexamethylenediamine, N-(1-naphthyl)ethylenediamine, 1-naphthalenesulfonylethylenediamine, hexamethylenediamine, or phenylenediamine.

REMARKS

Enclosed herewith in full compliance with 37 C.F.R. §§1.821-1.825 is a Substitute Sequence Listing to be inserted into the specification as indicated above. The Substitute Sequence Listing in no way introduces new matter into the specification. Also submitted herewith in full compliance with 37 C.F.R. §§1.821-1.825 is a disk copy of the Substitute Sequence Listing. The disk copy of the Substitute Sequence Listing, file "2185-0577P.ST25.TXT", is identical to the paper copy, except that it lacks formatting.

No new matter is introduced by these amendments.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any

additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,
BIRCH, STEWART, KOLASCH & BIRCH, LLP

By _____
Raymond C. Stewart, Reg. No. 21,066

RCS/ETP/LPS

P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

Attachments: Disk Copy of Substitute Sequence Listing
Paper Copy of Substitute Sequence Listing
Copy of Notification

(Rev. 03/27/01)

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Please replace the paragraph beginning on page 2, line 24, with the following rewritten paragraph:

Examples of the peptide include, for example, a synthetic peptide such as Pyr-Lys-Arg-Pro-Ser-Gln-Arg-Ser-Lys-Tyr-Leu **(SEQ ID NO:1)**, D-Phe-octreotide, polylysine or the like, a hormone such as oxytocin, bradykinin or the like, and an antibiotic[s] such as valinomycin, colistin or the like.

In the Claims:

16. (Amended) The process according to claim 1, wherein the compound having an amino group is a chitosan tri- to deca-saccharide, a chitosan tri- to deca-saccharide having a reduced terminal reducing group, a galactosamine tri- to deca-saccharide, a galactosamine tri- to deca-saccharide having a reduced terminal reducing group, serum albumin, fibrinogen, galactosyl serum albumin, amylase, pepsin, IgG, Fab, Fab', thyroid-stimulating hormone, a growth hormone, prolamine, glutelin, Pyr-Lys-Arg-Pro-Ser-Gln-Arg-Ser-Lys-Tyr-Leu **(SEQ ID NO:1)**, D-Phe-octreotide, polylysine, oxytocin, bradykinin, valinomycin, colistin, an α-amino acid, a β-amino acid, a γ-amino acid, aniline, 4-methylaniline, 4-octylaniline, ethylamine, n-propylamine, isopropylamine, n-butylamine, sec-butylamine, isobutylamine, tert-butylamine, n-octylamine, n-decylamine, (1-naphthylmethyl)amine, N-methylaniline, N-methyl-4-ethylaniline, N-methyl-4-octylaniline, diethylamine, N-ethyl-N-propylamine, ethylenediamine, dansylethylenediamine, dansylhexamethylenediamine, N-(1-naphthyl)ethylenediamine, 1-naphthalenesulfonylethylenediamine, hexamethylenediamine, or phenylenediamine.

#7

SEQUENCE LISTING

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NAKAMURA, Daisaku

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2/26 #9

OIPE

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PATENT APPLICATION: US/09/971,929 TIME: 11:59:46

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